UPMC
LIFE CHANGING MEDICINE

June 24, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via: http://www.regulations.gov

ATTENTION: CMS-1716-P

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma;

The University of Pittsburgh Medical Center (UPMC) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) proposed rule "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals ".

The following are UPMC's views and concerns regarding several major provisions of the FY 2020 proposed Inpatient Prospective Payment System (IPPS) rule. Please note that detailed comments regarding Quality proposals will be submitted under separate cover by our Quality experts.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals (FR 19380-19381)

Background: The Benefits Improvement and Protection Act of 2000 (BIPA) mandates that the hospital wage index be adjusted to reflect the occupational mix of employees. The intent of this adjustment is to ensure that the wage index reflects only geographic differences in prices hospitals pay for labor and not differences in the mix of their employees. Pursuant to the statute, data on the occupational mix of each hospital is to be collected every three years.

Proposed Rule: CMS is proposing to apply the occupational mix adjustment to 100 percent of the FY 2020 wage index. After initial review of comments concerning Hospital Wage Index, CMS has chosen to use data based on calendar year 2016 for the one-year collection period to complete and submit the survey within the specified timeframe. The preliminary unaudited 2016 survey data was released July 12, 2017. For FY 2020, CMS is proposing to calculate the occupational mix adjustment factor using the same methodology that they used since the FY 2012 wage index. At this time, hospitals which do not comply with the survey submission are not penalized but will be assigned the average occupational mix adjustment for their labor market area. Included in the revised 2013 occupational mix survey method, hospitals will be obligated to provide an explanation for not submitting the survey. CMS indicated that future analysis will be completed to determine the potential of penalties for non-compliant hospitals.

Response: UPMC believes that all hospitals should be obligated to submit their occupational mix surveys within the specified timeframe to CMS. A penalty should be assessed to non-compliant hospitals and consideration by CMS should be made so the penalty does not affect compliant providers. Wage Index is an essential part of the Medicare reimbursement equation and a provider's failure to complete the required surveys jeopardizes an accurate wage index calculation for all hospitals. However, pending the outcome of the analysis by CMS with regards to the concept of Commuting Based Wage Index (CBWI) and the Institute of Medicine Study on Medicare's Approach to Measuring Geographic Variation in Hospitals Wage Costs, UPMC fully supports the elimination of the occupational mix survey and the significant reporting burden it creates.

Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications (FR 19382-19387)

Background: The Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought. Prior to FY 2018, applications were required to be mailed or delivered to the MGCRB, with a copy also provided to CMS.

Proposed Rule: Beginning with applications to reclassify for FY 2020, the policy was revised to allow an electronic application to be filed through the MGCRB module (OH CDMS). Submitting a copy to CMS would result in hospitals having to complete their application information in a different format than what is required by the MGCRB. CMS is proposing to eliminate the requirement that an electronic copy of the application also be sent to them.

Response: UPMC supports the proposal to no longer require an additional application be submitted to CMS. The module used by MGCRB will allow CMS to verify reclassification statuses. This will be less of a burden on hospitals.

Proposals to Address Wage Index Disparities between High and Low Wage Index Hospitals (FR 19393-19399)

Background: In the FY 2019 IPPS/LTCH PPS proposed rule, CMS requested public comments for policy changes to the Medicare Wage Index. Many of the comments received reflect concerns over the current wage index system and disparities between high and low wage index hospitals.

Also, of concern is the calculation of the rural floor, and how hospitals in certain states can manipulate the wage index system to attain higher wages for urban facilities. The rural floor policy was addressed by the Office of the Inspector General in the November 2018 report on the vulnerabilities that exist in the Hospital Wage Index System. In its report the OIG found the rural policy was creating significant disparities in wage index and, in some cases, resulted in situations where all hospitals in a State received a wage index higher than that of the single highest wage index urban hospital in the State.

Proposed Rule: CMS is proposing to increase the wage index values for hospitals with a wage index in the lowest quartile of the wage index values across all hospitals. For FY 2020, the 25th percentile wage index value is 0.8482. The proposed increase would be equal to half the difference between the final wage index value for a hospital and the 25th percentile wage index value for that year across all hospitals. This proposal would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals enough time to be reflected in the wage index calculation. To maintain budget neutrality for the low wage index proposal, CMS is proposing to decrease the wage index value for hospitals in the highest quartile using the same methodology. This would include any hospitals above the 75th percentile of wage index values which is equal to 1.0351. CMS is also proposing to remove urban to rural reclassifications from the calculation of the rural floor. Beginning in FY 2020, the rural floor would be calculated without including the wage data of urban hospitals that have reclassified as rural. For hospitals that would be negatively impacted by the proposed wage index decrease, CMS is proposing for FY 2020, a transition wage index to help mitigate significant decreases. Under this proposal there would be a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. CMS is proposing to apply a budget neutrality adjustment to ensure that estimated aggregate payments under the proposed transition for hospitals negatively impacted would equal what estimated aggregate payments would have been without their proposed transition. The budget neutrality adjustment factor of 0.998349 is proposed to be applied to the FY 2020 standardized amount.

Response: UPMC commends CMS for their proposal to address the growing disparity between high and low wage index hospitals through its increase of the wage index for those hospitals with values in the lowest quartile. This proposal allows those small and rural hospitals to recruit and retain the clinical staff necessary to continue providing essential care in those communities.

While supportive of this initial proposal, UPMC is requesting CMS further amend the Proposed Rule to address the AWI for Pittsburgh, plus seven additional CBSAs that do not benefit from the currently proposed revision to the wage index methodology.

The Pittsburgh CBSA has seen a continued decline in its AWI, ultimately costing the hospitals more than $1 billion during the past 20 years. This equates to an 11.7% decline in the AWI. Hospitals continue to provide salary increases despite the decline in AWI. We are requesting CMS further amend the Proposed Rule impacting hospitals in eight CBSAs to have their Wage Index increased by 50% of the decline experienced since FFY 2000. CBSAs would meet the criteria for inclusion by applying the following methodology:

- For those CBSAs not otherwise benefiting from the implementation of the 25/75 criteria within the Proposed Rule (a second tier of qualification);
- With a Wage Index below 1.00;
- With a Wage Index decline of greater than 10 percent over the past 20 years (FFY 2000 – 2019);
- Qualifying CBSAs and hospitals will have their AWI increased by 50% of the decline experienced since FFY 2000; and,
- Implement this 10% decline methodology for these CBSAs for the same four year period as proposed for the 25/75 revision to the wage index

We believe this methodology is very similar to that used in the Proposed Rule for those rural CBSAs in the lower quartile that have been significantly impacted by the current wage index structure. This adjustment provides a stop-gap for hospitals that have experienced significant declines in their AWIs.

UPMC is appreciative of CMS' review of comments and suggested AWI amendment.

Proposed Payment Adjustments for Medicare Disproportionate Share Hospitals (DSH) (FR 19406-19423):

Background: Section 1886(d)(5)(F) of the Social Security Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 3133 of the Affordable Care Act (ACA) provides that a subsection (d) hospital that would otherwise receive a disproportionate share hospital payment will receive two separately calculated payments. The first portion is 25% of the Medicare Disproportionate Share Payment (DSH) that the hospital receives under current law, referred to as the Empirically Justified Medicare DSH payment. The remaining 75% of the payment is calculated using three factors. Factor 1 is CMS's estimate of 75% of the amount of Medicare DSH payments that would have been paid under the DSH methodology prior to ACA. For Factor 2, the 75% pool will be further reduced by the percentage of change in uninsured individuals. Factor 3 is equal to the percentage of uncompensated care relative to all hospitals eligible for DSH, that represents the quotient of the amount of uncompensated care that is a specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital for a period selected by the Secretary.

Proposed Rule: Beginning in 2014, CMS added a new section to the Patient Protection and Affordable Care Act (ACA) under Section 3133 to modify the methodology for computing the Medicare DSH Payments. CMS revised the claims payment methodology to adjust the interim claim payments to 25% of what would have otherwise been paid. The remaining 75% is the product of the three factors. CMS is proposing the following for FY 2020:

Factor 1: CMS is using the most recently available projections of Medicare DSH Payments for FY 2020 as calculated by CMS's Office of the Actuary. The proposed rule estimates will be based on the Actuary's December 2018 estimate for FY 2020 of $16.857 billion, which is then reduced by the Empirically Justified DSH payment of $4.214 billion to arrive at the Justified DSH Uncompensated Care payment pool of $12.643 billion, or 75% of original DSH payments that will be redistributed as Uncompensated Care (UC) DSH payments. This estimated Uncompensated Care pool will exclude Sole Community Hospitals paid under the hospital- specific rate, Maryland hospitals, Hospitals Participating in the Rural Community Hospital Demonstration, and Critical Access Hospitals.

Factor 2: Section 1886(r)(2)(B) of the Social Security Act provides that for each fiscal year from FY 2014 through FY 2017, the source of the estimated percentage of the population that was uninsured and under the age of 65 should be used in the computation of Factor 2 based on the estimates from the Director of the Congressional Budget Office (CBO). The Act permits the use of data sources other than the CBO estimates to determine the percent change in the rate of uninsured beginning in FY 2018, and no longer requires that the percentage of uninsured individuals be limited to those who are under 65 years of age. Therefore, after consideration of available data sources, as well as the reliability, timeliness and accuracy of the data, CMS has determined, beginning with FY 2018, that the best source of the uninsured population for factor 2 will be derived from CMS's Office of the Actuary (OACT). CMS's proposed estimated uninsured calculation for FY 2020 of 1 minus the "percentage change in the uninsured" points results in a 67.14% change or $8.489 billion.

Factor 3: The calculation methodology for Factor 3 was revised by CMS beginning in FY2018. Factor 3 is a hospital-specific value used to determine each subsection (d) hospital's estimated share of the Uncompensated Care Pool. Factor 3 is applied to the product results of Factor 1 and Factor 2 to determine the amount of uncompensated care that each hospital will receive. For FY 2020, CMS is proposing to use Worksheet S-10 data from FY2015 cost report data to calculate Factor 3 for FY2020. However, CMS is also proposing an alternative method using FY2017 data. CMS recognized for FY2019 that using data from three cost reporting periods will prevent undue fluctuations in the amount of uncompensated care payments to hospitals from year to year. CMS is aware and believes that for FY2020 mixing audited & unaudited data for individual hospitals by averaging several years of data could lead to less smooth results. CMS believes that using FY 15 audited data and FY16 unaudited data would dilute the effect of auditing efforts and produce variability in the calculation by using 3 years of data. CMS commented in FY2019 that based on the outcome of the examination of data from FY2016 Worksheet S-10, CMS may determine for FY2020 that multiple years of S-10 data is no longer necessary for calculating Factor 3. For purposes of the FY2020 proposed rule CMS has used the most recent HCRIS extract that was updated February 15, 2019. CMS expects to use the March 2019 updates of HCRIS files for the final rule.

Response: UPMC continues to have concern with the use of Worksheet S-10 in the calculation of Uncompensated Care Payments. While supportive of CMS' efforts to implement an audit protocol, UPMC maintains that reviews should be handled in the same manner as Worksheet S-3 for the wage index to allow for accuracy and consistency.

Results of recent reviews clearly demonstrate the variability and inconsistency among both hospitals preparing Worksheet S-10 and the MACs auditing those same worksheets. The resulting variability is further exacerbated by a selection of a sampling of hospitals versus 100% review.

Unresolved concerns and issues are as follows:

Ensuring the accuracy of Worksheet S-10, as it is incorporated into the calculation of Factor 3, certifies consistency and completeness of the data for this to be an effective tool used to determine how much uncompensated care hospitals will be allocated. Any misinterpretation of Worksheet S-10 instructions that could potentially overstate/understate an individual hospital's uncompensated care, no matter how unintentional, affects every other hospital eligible for Medicare DSH UC payments. Review of all hospitals versus a sampling is critical in mitigating misinterpretation and subsequent misallocation of these funds so critical to DSH hospitals.

For F2020 CMS is proposing to utilize a single year of Medicare cost report data from the audited FY2015 S-10 worksheet and not continue the three-year averaging process for Factor 3. UPMC is supportive of Worksheet S-10 reviews utilizing well defined audit standards and protocols that are consistently applied across all hospitals. Numerous concerns have been raised by the hospital industry over recent reviews of a subset of hospitals. Issues include the following:

- Use of both audited and unaudited data in determination of Factor 3
- MAC estimation "expected payments" unsupported by cost report instructions and inconsistently applied
- Lack of standard application of Worksheet S-10 review protocols (i.e. extrapolation methods)
- MAC review and misinterpretation of hospital charity care policies

Additionally, CMS is requesting public comment on whether unaudited FY2017 S-10 data should be used instead of the audited FY2015 S-10 data. This alternate proposal does not adequately address the inconsistencies among the hospitals reporting the Worksheet S-10 data as described above. Any misinterpretations by an individual hospital can impact all other hospitals. UPMC would support handling the use of Worksheet S-10 the same way as Worksheet S-3 for the wage index to allow for accuracy and consistency.

In conclusion, UPMC believes that Worksheet S-10 has the potential to be an appropriate source in determining uncompensated care costs. That requires safeguards be in place to both mitigate the unpredictability of individual hospital interpretations of Worksheet S-10 and ensure consistent application of standard MAC audit protocols on the calculation methodology for Factor 3. In the interim, UPMC respectively asks CMS to consider a different methodology to calculate Factor 3 for FY2020 that would protect the integrity of Uncompensated Care payment allocation among hospitals.

Proposed Changes Related to CAHs as Non-providers for Direct GME and IME Payment Purposes (FR 19406, 19446-19448)

Background: Under regulations governing direct GME payments to non-provider sites (42 CFR 413.78(g) and the corresponding IME regulations at 42 CFR 412.105(f)(1)(ii)(E)), a hospital can include in its FTE counts residents training in a non-provider setting if the hospital incurs the residents' salaries and fringe benefit costs while training at that site, in addition to meeting other requirements. At the same time, under CAH payment regulations at 42 CFR 413.70, CAHs that train residents in approved residency training programs are paid 101% of the reasonable costs associated with training residents in approved programs. Many have expressed concerns that CAHs are not considered non-provider sites for purposes of direct GME and IME payments, so that current policy is creating barriers to training residents in rural areas and thereby hindering efforts to increase the practice of physicians in rural areas. Section 5504 of the Affordable Care Act amended Sections 1886(d)(5)(B)(iv)(II) and 1886(h)(4)(E) to reference the term "non-provider". Several changes were made to the requirements a hospital must meet to include Residents training in a non-provider setting in its FTE count.

These include:

Adding the requirement that a hospital need only incur the Resident's salaries and fringe benefit costs to count the Resident (rather than incurring all or substantially all of the costs of training at the non-provider site);

Including the provision to enable more than one hospital to count FTE Residents training at a single non-provider site.

Section 1861(e) of the Act states that the definition of a "hospital" does not include a CAH. A CAH under Section 1861(u) of the Act is a "provider of service" primarily engaged in patient care. Also, the term "non-provider" is not explicitly defined. Due to these factors, CMS believes there is flexibility under current statutory language to consider a CAH as a "non-provider" setting for direct GME and IME payment purposes.

Proposed Rule: Effective with portions of the cost reporting periods beginning October 1, 2019, a hospital may include FTE Residents training at a CAH in its FTE count as long as it meets the non-provider setting requirements set forth at 42 CFR 412.105(f)(1)(ii)(E) and at 42 CFR 413.78.

The above does not change the fact that a CAH may continue (at the same time) to incur the costs of training Residents in an approved Residency training program and receive payment based on 101% of the reasonable costs of the training. The proposed changes are intended to support the training of Residents in rural and underserved areas.

Response: UPMC supports CMSs proposal to modify the current policy, such that a hospital could include residents training in CAH in its FTE count as long as the non-provider meets the requirements in 42CFR413.78. This modification will prevent barriers for residents to train in rural areas in addition to increasing practice of physicians in rural areas.

Proposed Changes to the Provider Reimbursement Review Board Appeals (FR 19579)

Background: Established in 1972, the Provider Reimbursement Review Board (PBBR) was established in order to allow healthcare providers the opportunity to appeal Medicare Cost Report payment disputes and absolve any dissatisfaction a healthcare provider might have with reimbursement determinations made by the MAC. One of the biggest issues that CMS is currently facing, is the backlog of Medicare Cost Report appeals that have been made in recent years. Since 2015, CMS has averaged over 3,000 filed appeals a year. In that same timeframe, CMS has only been able to resolve 2,200 appeals a year. Due to this backlog, it is currently taking upwards of four years to go through the appeal process. There are several ways in which CMS is hoping to resolve these appeal backlog issues. Providers would be a given a standard format and structure for submitting Medicare Cost Reports and supporting documentation. Clear standards of documentation would also be set in place for the auditing of cost reports. By enhancing the E-filing process, providers will be able to receive more automated correspondence notifications as well as access to see where they are in the cost report reopening process. CMS is also looking to utilize artificial intelligence to design risk protocols. These protocols would create algorithms that could look through archives of appeal resolutions and present results on how to handle a current appeal with information on how a previous appeal was resolved. Lastly, CMS is looking to improve on the process of claiming DSH Medicaid Eligible Days for both cost report submission and settlement process.

Proposed Rule: As part of the Proposed Rule, CMS is requesting public comment on PRRB appeals related to a provider's Medicaid fraction in the DSH payment adjustment calculation. They are proposing two solutions on how to reduce the number of appeals regarding the submission of a provider's additional MA DSH days.

- Proposal 1 instead of filing appeals, providers could use the reopening process within the three-year reopening window; CMS would issue directives requiring MAC's to reopen cost reports at a specific time and set a period during which providers could submit updated MA data.
- Proposal 2 CMS would allow a one-time option of resubmitting cost reports with the updated MA eligibility data and undertake rulemaking to determine the timeframe after the close of a cost reporting period to use this option

Response: UPMC is supportive of CMS efforts to reduce the backlog of appeal requests. However, it is not clear how either Proposal 1 or Proposal 2 will be effective in reducing the large volume of DSH day appeals. Providers are currently afforded the opportunity to amend or request reopening of cost reports to add days. Perhaps the backlog could be reduced through education efforts directed to Providers and MACs about options currently available outside of appeals.

Proposed Payment for Chimeric Antigen Receptor (CAR) T-Cell Therapy (FR 19180-19182, 19278-19279)

Background: CAR T-cell therapy is an innovative new form of immunotherapy that uses a patient's own altered T cells. The patient's T cells are collected from the blood, separated and then modified to produce special structures called chimeric antigen receptors (CARs). These CAR T cells are reinfused into the patient where the new receptors enable them to identify to and attack the patient's cancer cells.

Two CAR T-cell therapy drugs received FDA approval in 2017. KYMRIAH (manufactured by Novartis Pharmaceuticals Corporation) was approved for the use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. YESCARTA (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment. Procedures involving the CAR T-cell therapy drugs are currently identified with ICD-I0-PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which both became effective October 1, 2017.

For CY 2019, CMS assigned these services to MS-DRG 016, "Autologous Bone Marrow Transplant with "CC"/"MCC" or T- Cell Therapy". For CY 2020, CMS is proposing to keep CAR T-cell therapy assigned to MS-DRG 016 as they feel it is premature for any changes with insufficient comprehensive clinical and cost data.

Proposed Rule: CMS is proposing to maintain the current MS-DRG of 016 for CY 2020 for CAR T therapy. Although the agency has concerns of current claims data, they are seeking comments on payment alternatives for CAR T-cell therapies, including a potential new MS-DRG. CMS is also seeking comments

on the appropriate way to develop a relative weight if they were to proceed with a new MS-DRG and whether clinical trials data should be excluded when developing the relative weight. CMS is also seeing comments on whether the IME and DSH payments should not be made to any cases assigned to any new MS-DRG.

The agency is also seeking public comments on whether they should consider using a specific CCR for the CAR T-cell specific ICD-10-PCS procedure codes.

Finally, the agency invites public comments on some potential changes on New Technology Add on Payments (NTAP) for CAR T-cell therapy. For FY 2020, CMS is proposing to continue new technology add-on payments for KYMRIAH® and YESCARTA®. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9 of the proposed rule, the agency is proposing that the maximum new technology add-on payment amount for a case involving the use of KYMRIAH® and YESCARTA® would be increased to $242,450 for FY 2020; that is, 65 % of the average cost of the technology with discharges occurring on or after October 1, 2019.

The agency is proposing this as either through current NTAP calculations or via a fixed add on payment.

Response: UPMC, along with numerous other organizations, including the American Hospital Association [AHA] submitted comments to CMS last year in response to the FY 2019 IPPS Proposed Rule. For calendar year 2019, CMS finalized reassigning CAR T to MS-DRG 016. We welcome this additional opportunity to submit comments on options to ensure adequate reimbursement of CAR T for CY 2020. We have the unique perspective of having treated 25 patients over the past year and can speak to the current challenges.

Our experience and patient response rates echo the outcomes presented at national conferences, proving CAR T to be an incredible breakthrough in Cancer treatments. Multiple patients at UPMC with limited treatment options have experienced dramatic improvement or even complete clinical responses to the therapy.

We understand the concerns of CMS in creating a CAR T specific MS-DRG in light of the relatively small number of claims and clinical data. However, the current Medicare payment structure creates a shortfall in reimbursement for these highly complex and high acuity patients. Hospitals will not be able to sustain the significant losses that result under current IPPS reimbursement methodologies. We urge CMS to ensure facilities cover costs in order to provide this emerging lifesaving treatment to Medicare beneficiaries. When CMS is ready to create specific MS-DRGs for CAR T, we urge the agency not to use clinical trial claims in the calculation of relative weights. If the clinical trial claims did not include the high cost products on the claim, the relative weight calculations will not accurately reflect true cost of providing this treatment.

Although we appreciate the fact that CMS acknowledges current NTAP payment policies need to be reviewed and modified, UPMC is not in support of the proposed 65% NTAP payment either by the current CMS calculations or a fixed NTAP. The 65% proposed payment will still leave a significant short fall that cannot be sustained. There are no substitutes for these products, and providers have no ability to negotiate the costs. As a personalized cellular therapy, CAR T products cannot be purchased in bulk, nor can providers obtain discounts from manufacturers as we do for other drug therapies. Therefore,

the current NTAP payment methodology or the proposed updated NTAP at 65% is not an appropriate mechanism for addressing the new CAR T technology costs.

It is imperative for CMS to take proactive steps now to ensure that facilities can cover the cost of these initial breakthrough cell and gene therapies, as well as future innovations in this area. This will ensure Medicare beneficiaries will have full access to this innovative treatment.

While CMS has invited public comments on several alternative approaches to pay for CAR-T therapy, UPMC believes that the agency should adopt an option that utilizes the Average Sales Price (ASP) to cover the cost of the CAR T product. As NTAP payment is non-budget neutral, we recommend that CMS utilize the dollars it has set aside for NTAP to provide separate CAR T payment based on ASP. This process would enable the agency to use funds outside of the regular MS-DRG system, therefore averting any budget neutrality issues, and thus pay appropriately for CAR T therapy.

This concept is not entirely new, as CMS uses a similar ASP-based approach to pay for hemophilia blood clotting factors. We believe the ASP option is the simplest for the agency to implement since the infrastructure is already in place to adopt this payment method for CAR T. Additionally, this method would be easy for providers to operationalize and would provide fair and appropriate reimbursement for the product cost of this overall therapy.

An ASP-based add-on payment for the CAR T product added to MS-DRG 016 could be updated quarterly. It would, therefore, recognize any manufacturer discounts to CAR T well-before the annual IPPS rulemaking process. Quarterly updates to the ASP for CAR T will help ensure fair reimbursement for the product without the risk of overpayment. Any potential outlier payments would be calculated only based upon charges for all other patient care costs. This approach also aligns payment for CAR T more closely between the IPPS and the Outpatient Prospective Payment System (OPPS) and would remove any inadvertent financial incentives based on site of care.

UPMC is pleased that CMS is seeking comments on this issue, and by the agency's recognition that the current reimbursement is not sustainable for providers. We would be happy to provide additional information to assist the agency in creating policies to improve CAR-T reimbursement.

Proposed Changes to Specific MS–DRG Classifications (FR 19170-19235)

Background: CMS is proposing changes to several MS-DRG Classifications for 2020. The agency invites public comments on each of the MS-DRG classification proposed changes. The proposed changes are a result of CMS analysis of claims data and consultation with clinical advisors. As explained in previous rulemaking, CMS will consider changes to existing MS-DRG assignment if the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS-DRG.
In order to consider if a new MS-DRG is to be created, CMS will apply the following criteria to determine if the creation of a new complication or comorbidity ("CC") or major complication or comorbidity ("MCC") subgroup within a base MS-DRG is warranted:

- A reduction in variance of costs of at least 3 percent;

- At least 5 percent of the patients in the MS-DRG fall within the "CC" or "MCC" subgroup;
- At least 500 cases are in the "CC" or "MCC" subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups. In order to warrant creation of a "CC" or "MCC" subgroup within a base MS-DRG, the subgroup must meet all five of the criteria.

Proposed Rule: CMS is proposing changes to several MS-DRGs

Trans catheter Mitral Valve Repair (TMVr) procedures, such as the MitraClip™ , currently map to MS-DRGs 228 and 229 Other Cardiothoracic Procedures with and without "MCC"s. CMS proposes to reassign trans catheter Mitral Valve Repair (TMVr) and other trans catheter valve supplement procedures to revised MS-DRG 266/267 Endovascular Cardiac Valve Replacement & Supplement with and without "MCC"s.

Response: UPMC supports the move of Trans catheter mitral valve repair to TAVR DRGs 266-267

Payment change DRG 0215. CMS is proposing an additional reduction in payment on Impella procedures. This will result in a net 43% reduction in payment over the last three years.

Response: UPMC asks that CMS delay the proposed changes for MS-DRG 215. The coding for Impella Heart devices has undergone numerous changes over the last two years. The American Hospital Association has issued five separate coding guidance alerts since October of 2016, with the last being released February of 2018. It appears hospitals have been slow to implement these changes as claims data reveals potential missing ICD-10 procedure codes. A significant number of claims do not have the correct combination of the insertion and removal codes. In addition, claims data reveals the 68% of claims do not include the cost of the Impella device on the inpatient claim. As a result, CMS is not receiving the true cost of these procedures. We ask CMS maintain the FY19 payment rate in FY20 to avoid an access to care issue for patients.

Peripheral ECMO DRG assignment: In March of 2018, the ICD– 10 Coordination and Maintenance Committee Meeting finalized the creation of three new procedure codes to identify and describe different types of ECMO treatments currently being utilized. Code 5A1522F (Extracorporeal Oxygenation, Membrane, Central) was assigned to Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure). Codes 5A1522G (Extracorporeal Oxygenation, Membrane, Peripheral Venoarterial) and 5A1522H (Extracorporeal Oxygenation, Membrane, Peripheral Venovenous) were assigned to various other MS-DRGs.

Based upon further review, CMS is proposing to reassign the following procedure codes describing peripheral ECMO procedures from their current MS–DRG assignments to Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure). If this proposal is finalized, CMS would make conforming changes to the titles for MS– DRGs 207, 291, 296, and 870 to no longer reflect the "or Peripheral Extracorporeal Membrane Oxygenation (ECMO)" terminology in the title. If finalized, the procedures would be defined as non- O.R. affecting the MS–DRG assignment for Pre-MDC MS–DRG 003.

UPMC Response: UPMC supports the 2020 proposal to assign all ECMO ICD-10 PCS codes (5A1522F, 5A1522G and 5A1522H) to Pre-MDC MS-DRG 003 for FY 2020. All ECMO cases, regardless of the cannulation method require significant facility infrastructure as well as coordination by a multidisciplinary team in the course of a lengthy ICU management for these critically ill patients. As such, the majority of the costs associated with ECMO are unrelated to the method of vascular cannulation.

Proposed Add-On Payments for New Services and Technologies for FY 2020 (FR 19275-19373)

Background: Established in 2001, the NTAP Program was designed by Congress to encourage the adoption of new and costly medical technologies in the inpatient hospital setting. It was designed to partially compensate hospitals for using new products that are not reflected already in Medicare's regular reimbursement calculations. Currently, the NTAP payment amount is to be paid at a maximum of 50% of the marginal cost of the new technology.

Proposed Rule: With the intent to support and improve beneficiary access to new technology, CMS is proposing a number of policies in order to streamline and facilitate access to New Technology Add-on Payments

- **Proposed NTAP Alternative Pathway for Devices:** Under this proposal, medical devices that receive US Food and Drug Administration (FDA) marketing authorization and are part of an FDA expedited program for medical devices (*e.,* Breakthrough Devices Program) would have a lower bar to be eligible for an add-on payment. Under this proposal, the medical device would only need to meet the cost criterion to receive the add-on payment (and not the substantial clinical improvement criterion). This change would begin with applications received for NTAPs for FY 2021.
- **Proposed Calculation of NTAP:** Currently, Medicare pays a marginal cost factor of 50% of the estimated costs of the case in excess of the full diagnosis-related group payment, up to a maximum of 50% of the costs of the technology. Because of increasing costs of new medical technologies, CMS is concerned that 50% may not be adequate. CMS proposes to increase the add-on payment beginning in FY 2020 from 50% to 65%. As a result, the maximum add-on payment in the proposed rule would increase from $186,500 to $242,450 for CAR T-cell therapy.
- **Request for Information on the NTAP Substantial Clinical Improvement Criterion:** Stakeholders have indicated that they would like to better understand how CMS evaluates new technology applications for add-on payments, and would like the agency to provide greater predictability about which applications will meet the criterion for substantial clinical improvement. CMS is considering potential revisions to the substantial clinical improvement criterion under the IPPS NTAP policy and the hospital outpatient transitional pass-through payment policy for devices. CMS seeks comments on the type of additional detail and guidance that would be useful to the public and NTAP applicants for NTAPs would find useful. These comments will be used to inform future rulemaking.

Response: UPMC appreciates the fact that CMS recognizes the adoption new technology services is sometimes challenging as the cost of the new technology typically falls short of the inpatient reimbursement. We also understand the need of CMS to have several years of claims data in order to

properly create a new MS-DRG or place a new technology service in an existing DRG which will cover cost. In the interim, facilities must make the difficult choice to offer these services at a financial loss or not adopt innovative practice. With the intent to support and improve beneficiary access to new technology, CMS is proposing a number of policies changes in order to streamline and facilitate access to the add-on payments. UPMC is supportive of the proposed changes with some suggested revisions.

We are pleased CMS is considering options to streamline the process for the NTAP approvals. We support the proposed NTAP alternative pathway for devices. As these devices have already have received US Food and Drug Administration (FDA) marketing authorization and are part of an FDA expedited program for medical devices, the medical device would only need to meet the cost criterion to receive the add-on payment.

We do appreciate that CMS is proposing to increase the NTAP payment from 50% of the marginal cost of the new technology to 65%. However, depending on the new technology, this will still leave a shortfall in covering cost. This shortfall can be dramatic as the cost of new technology increases. Specifically, looking at CAR T, the increase from 50% to 65% of cost will increase the NTAP payment from $186,500 to $242,450. There will be a remaining shortfall in covering product cost of well over $150,000. This is not sustainable over time.

In addition, UPMC requests that CMS increase the NTAP payment to 100% of the marginal cost of the new technology. UPMC would also ask CMS consider simplification of the NTAP payment methodology. Currently, if the costs of discharge exceed the Medicare Severity Diagnosis Related Group (MS-DRG) payment, Medicare will make an add-on payment under the NTAP program equal to the lesser of 50% of the costs of the new medical service or technology or 50% of the amount by which the costs of the case exceed the standard DRG payment.

As we understand there may be wide variations across hospitals in charge mark-ups and cost estimates for cases that include paying NTAP qualifying new technologies, there is the potential of skewed NTAP distribution across hospitals.

We ask that CMS consider paying a % (preferably at 100% instead of the 65% proposed) of the new technology cost and not utilize the lesser of 50% of the costs of the new medical service or technology or 50% of the amount by which the costs of the case exceed the standard DRG payment.

We understand that NTAP payment is not budget neutral, and any increase in the NTAP payment will not be at the expense of other DRG payment rates.

We also understand the current NTAP program is underutilized based upon current criteria. In addition to low manufacturer application rates, CMS denies a large proportion of NTAP applications each year as current policies prevent higher approval rates. Of the 26 medical device manufacturers that had applied for NTAPs between fiscal year (FY) 2012 and 2018, only 11 were approved. To date, CMS has only approved about a third of NTAP applications. The most cited reasons for rejection are failure to meet the "newness" criterion and the "substantial clinical improvement" criterion.

In summary, we are pleased CMS is proposing several significant changes to the NTAP policies as the current NTAP program has not been fully utilized. As the original intent of the NTAP program was to encourage adoption of new, costly technologies by enabling a reimbursement resource until sufficient claims data is available to assign to a proper MS-DRG, updates to the current NTAP are needed. Although we appreciate the increase from 50 to 65% of the marginal cost of the new technology, we request CMS increase the NTAP payment to 100%.

Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights (FR 19235-19250)

Background: The Inpatient Prospective Payment System mandates an annual review of the ICD-10 codes as well as a review of the list of codes that qualify as a complication or comorbidity ("CC") or a major complication or comorbidity ("MCC") when used as a secondary diagnosis.

Proposed Rule: The 2020 IPPS proposed rule includes 324 proposed ICD-10-CM code changes for fiscal year 2020. Of these changes, there are 273 new codes, 30 revised, and 21 that will be discontinued. In addition to these changes, CMS is making changes to nearly 1,500 "CC"M'MCC" designations.

Response: UPMC has conducted an extensive review of the proposed changes to the "CC" or "MCC" designations. Many of the co-morbidities that are being downgraded to either a "CC" or non-"CC" are the same co-morbidities that require the most resources to care for the patient. We ask CMS to review and consider our comprehensive review of these proposed changes as listed below.

Re-designation of malignancies as "non-CC"

The 700+ codes for malignancies that are proposed for re-designation as "non-CC" make up 11% of our patient population based on last year's coding statistics. Medicare data is by and large compiled from the elderly, who often have multiple other medical conditions that demand more intense care. These conditions drive the DRG assignment. These patients may also be receiving palliative care rather than aggressive therapy due to age and the presence of other medical problems. As a major health system with a world-class cancer center this will not only have an impact on reimbursement for very costly treatments and surgeries but may also impact severity of illness and risk of mortality scores. A demotion of the designated malignancy codes to "non-CC" status may adversely impact the DRG of those younger adult and pediatric patients with the same malignancies. Younger patients often do not have a multitude of other illnesses that would offset the impact of the malignancy in the calculations of resource allocations as is demonstrated in the older patient. The younger patient often pursues multiple modalities of treatment for the diagnosed malignancy and these treatments have an associated risk of adverse effects, requiring acute care interventions.

Acute blood loss anemia re-designated as "non-CC"

Acute blood loss anemia makes up 5% of our inpatient population and this condition is monitored closely with daily labs costing approximately $800 and treated with blood transfusion costing $1300. In addition to those direct costs, acute blood loss anemia may lead to hypotension, shock, and organ damage and death. Intense monitoring and resources are involved in managing these patients. There are many procedures that are associated with excessive blood loss including orthopedic procedures, cardiovascular procedures, liver transplantation and hepatic resections, as well as spine surgeries. In addition to those elective surgeries, trauma centers contend with acute blood loss anemia frequently (1). Our institution performs all of those procedures and is a trauma center. In addition, looking at this from a quality reporting perspective, this may impact severity of illness scores of the patient and falsely reflect they are not sick.

1. Mannucci PM and Levi M. prevention and treatment of major blood loss. N Engl J Med 2007; 356:2301-11.

Downgrading of severe protein calorie malnutrition from an "MCC" to a "CC"; upgrade of moderate protein calorie malnutrition to an "MCC"

The proposed changes with the new rule relating specifically to malnutrition does not appear to make sense from a clinical perspective. Moderate malnutrition is proposed as an "MCC" while severe malnutrition is proposed to be downgraded to a CC despite the terminology indicating an increase in severity and needs.

Severe persistent asthma and status asthmaticus

Another example is acute exacerbation of severe persistent asthma being proposed as an "MCC" yet status asthmaticus, being a more severe respiratory condition and not sure how the determination was made to consider these two conditions equal in severity.

Downgrading of Ruptures of chordae tendineae or papillary muscle "MCC" to "CC"

CMS is proposing that rupture of the chordae tendineae or the papillary muscle not due to an acute myocardial infarction that may cause mitral regurgitation be classified as a CC rather than MCC. Patients with acute mitral regurgitation are "often gravely ill with significant hemodynamic abnormalities that require urgent medical and usually surgical treatment" (1). Rupture of the chordae tendineae often occur in the setting of other disease states, which compounds the severity of illness for the patient. Those diseases include infective endocarditis and rheumatic heart disease (2). These patients require intense resources including antibiotics, surgical intervention, ICU care if there are serious hemodynamic consequences to the rupture. Studies have shown that the 30-day mortality rate for patients with acute rupture can be as high as 23% (3). For these reasons, we contend that this should remain an MCC.

1. Stout KK, Verrier ED. Acute Valvular Regurgitation. Circulation. 2009; 119(25):3232.
2. Otto, C. Acute mitral regurtitation in adults. Up To Date. 2019.
3. Lorusso R et al Mitral valve surgery in emergency for severe acute regurgitation: analysis of postoperative results from a multicenter study. Eur J Cardiothorac Surg 2008; 33(4):573.

Downgrading of Viral infectious gastroenteritis and colitis unspecified from a "CC" to a "non-CC"

We disagree with proposal to downgrade infectious gastroenteritis and colitis unspecified from a "CC" to a "non-CC." The medical literature is clear that stool studies are not usually necessary or commonly routinely ordered to treat this condition. The population of adults who are highly considered to be hospitalized for this condition are those who are 65 and over. Patients at high risk of poor outcomes and thus require more resources are those with immunodeficiencies, inflammatory bowel diseases, on immunosuppressant therapy, diabetes, rheumatological conditions, valvular heart disease. (1) At our institution, we care for a large percentage of immunocompromised patients. We have a large cancer and transplant center. In addition, we care for many with HIV, rheumatologic diseases and valvular disorders. Reducing this from a cc to a "non-CC" will affect our resources and may affect how we can best treat our Medicare population.

1. Alexandraki I and Smetana G. Acute viral gastroenteritis in adults. Up To Date. May 2019.

Downgrading of Myelodysplastic syndrome from "CC" to a "non-CC"

Myelodysplastic Syndrome should remain a "CC". This patient population is profoundly ill and requires intense resources for treatment. Even if they are hospitalized for another condition, MDS has significant implications for their prognosis. Most patients diagnosed with MDS die (1). It is reported that an increased patient's age is a poor prognostic factor (2). This reduction from a cc to a non-cc adversely reflects the resource allocation that is required for this age group.

1. Estey E and Schrier S. Up To Date. May 2019.
2. Kantarjian H O'Brien S et. Al. Cancer. 2008;113(6):1351.

Downgrading of Most Sickle Cell Disease Codes from an "MCC" to a "non-CC"

Sickle cell disease should remain a CC. This is a serious disease, that through vaso-occlusion, can lead to crisis, organ damage and death. This disease can lead to Acute chest crisis, joint complications, acute stroke, hepatic disease, chronic pain, pulmonary and hypertension (1). Those with sickle cell develop osteomyelitis, avascular necrosis, septic arthritis. For those with osteomyelitis and may require debridement, it is recommended to avoid if possible as it may precipitate Acute Chest Crisis. Overall, this disease requires intense resources in its management and by removing from the CC/MCC list, it will impact this population in a negative way.

1. Field J, Vichinsky E and De Baun, M. Overview of the management and prognosis of sickle cell disease. Up To Date May, 2019.

Downgrading of Acute Chest syndrome from an "MCC" to a "non-CC"

With respect to Acute Chest Syndrome, which is being proposed to be removed from the CC list, it is the second most common cause of hospitalization for this patient population (1). It is the most common cause of death. These patients are quite ill with pneumonia, hypoxia, fat emboli, infarction and various infectious pathogens including chlamydia, mycoplasma, viral, mixed infections, and Legionella. Older patients, those over 20 years old, fared worse with the Acute Chest Crisis (2). Many of these infections are opportunistic. This population is vulnerable to these infections and due to their underlying condition are sicker, require more care and may not fare as well as a healthy person. To downgrade this to a non-CC will limit resources for hospitals to care for these patients.

1. Castro O, Brambilla DJ et al. The acute chest syndrome in sickle cell disease: incidence and risk factors. The cooperative Study of Sickle Cell Disease. Blood. 1994;84(2): 643.
2. Vichinsky EP et al. Causes and outcomes of the acute chest syndrome in sickle cell disease. National Acute Chest Syndrome Study Group. N Engl J Med. 2000;342(25):1855.

Downgrading of splenic sequestration crisis from an "MCC" to a "non—CC"

Splenic sequestration crisis should remain an MCC. This is a very serious syndrome in which a large amount of the patient's total blood volume can be contained within the spleen which can then lead to hypovolemic shock and death. As stated previously under the acute chest syndrome section, this population is vulnerable to infections. In many cases, parvovirus B 19 infection may be the precipitating event for splenic sequestration (1). The mortality rate in this condition is as high as 10% to 15% (2, 3). Of those who survive, about half have another splenic sequestration crisis (4). Given the serious nature of this crisis, the potential for shock, death and recurrence, this should remain an MCC.

1. Smith-Witley K et al. Epidemiology of human parvovirus B 19 in children with sickle cell disease. Blood. 2004; 103(2): 422.
2. Emond AM. Colins R et al. acute splenic sequestration in homozygous sickle cell disease: natural history and management. J Pediatr. 1985;107(2):210.
3. Topley JM, Rogers DW et. al. acute splenic sequestration and hyper spleen is him in the first five years in homozygous sickle cell disease. Arch Dis Child. 1981;56(10):765.
4. Vivhinsky E. overview of the clinical manifestations of sickle cell disease. Up to date. May 2019.

Downgrading of hypercoaguable states to "non-cc"

Hypercoaguable states should remain a CC. Patients with activated protein C resistance, prothrombin gene mutation, thrombophilia, antiphospholipid syndromes, lupus anticoagulant syndromes are at increased risk for multiple adverse events related to the clotting disorder. They require more monitoring with blood work, medication adjustments and for patients who require surgery, need intensive monitoring of their coagulation studies and careful attention to medication management. Patients with these conditions are not on par with patients without these conditions. For that reason, it should remain a CC.

Downgrading of aplastic anemia, unspecified from "CC" to "non-CC"

Aplastic anemia should remain a CC. Regardless of specificity, aplastic anemia is a serious condition with profound comorbidity. "Aplastic anemia is a disorder of hematopoietic stem cells that cause pancytopenia and a hypo cellular bone marrow without splenomegaly. Affected patients typically present with recurrent infections due to neutropenia, bleeding episodes due to thrombocytopenia, and fatigue due to anemia. Patients with aplastic anemia are at a risk of life – threatening complications, especially when pancytopenia is severe" (1). These patients require intensive monitoring and treatment and are certainly not on equal footing with the rest of the population in regard to complications or comorbidities.

1. Schrier S. Treatment of aplastic anemia in adults. Up-to-date May 2019.

Downgrading of Anti-neoplastic chemotherapy induced thrombocytopenia from an "MCC" to a "CC"

We disagree with the downgrading of this condition from an MCC to a CC. Patients with drug-induced thrombocytopenia are very high risk for infection, spontaneous bleeding, and hemorrhage. Our institution cares for many patients with malignancies who suffer from chemotherapy induced thrombocytopenia. Many resources are directed towards their care including infection control, dietary management for patients with neutropenia, blood products including blood and platelets, frequent laboratory monitoring, and intense nursing care.

Downgrading of hypopituitarism from a "CC" to a "non-CC"

We disagree with the decision to downgrade this code to a "non-CC." Patients with this syndrome are at high risk for deleterious effects, including death. Patients with this syndrome have significant alterations in the hormones including ACTH, TSH, gonadotropins, growth hormone and prolactin. A patient with ACTH deficiency can lead to a cortisol deficiency. Without cortisol, the patient can succumb to cardiovascular collapse and severe tachycardia. These can lead to death. A lack of TSH may lead to bradycardia. Patients with this syndrome require monitoring of the hormones, adjustments to medications, and, when they are ill, close monitoring of their cortisol levels in order to prevent vascular collapse and death.

Downgrading of BMI weight related codes from "CC" to "non-CC"

We disagree with this decision. We agree with the statement provided by the Association of clinical documentation improvement specialists (ACDIS):

"I write today to submit our comments regarding the proposed designation change for ICD-10-CM codes Z68.41 (Body mass index 40.0-44.9 adult) and Z68.42 (Body mass index 45.0-49.9 adult) from "CC" to "non-CC" status. We appreciate and understand that the process of data analysis that indicates that these two Z codes do not consistently demonstrate a CC type impact as a secondary diagnosis. However, we believe that the actual clinical care of the patient with morbid obesity (defined by the Centers for Disease Control and Prevention as a BMI > 40) impacts resource use, health care costs, and needs for care that would not be reflected in the claims data that serves as the basis for CMS work.

It is our consideration that patients with a BMI > 40 have a significant impact on allocation of healthcare resources and should maintain the same comorbidity status. Some of the difficulties with morbidly obese patients are readily apparent to clinicians. Patients who are morbidly obese have higher rates of additional conditions such as diabetes, hypertension, heart disease, and certain cancers. Such patients are also physically harder to manage, causing difficulty for staff in lifting, turning, and ambulation. Their size may also hamper diagnostic efforts such as diagnostic radiologic studies or therapeutic procedures. The medical literature provides an extensive record of support for the premise that morbid obesity is linked to increased use of hospital resources and increased length of stay.

Patients with morbid obesity may also be linked to an increased incidence of work-related injuries. OSHA has recently noted the increase in musculoskeletal injuries reported by healthcare workers and found that they encounter unique risks because they "lift, reposition, and transfer patients who have limited mobility. Larger patients can pose particular challenges for safe handling1. Multiple states have enacted safe patient handling laws which require hospitals and other healthcare systems to acquire the

necessary equipment to safely lift and move patients2. Hospitals are also investing capital providing imaging and OR suites that can accommodate the larger patient. Given that the CDC estimates that nearly 40% of Americans are morbidly obese3, health care systems are absorbing significant impacts in injury, missed days of work, worker compensation claims, and purchase of capital equipment in caring for these patients.

These are resources that cannot be codified in CMS claims data, but should be considered in determining the comorbidity status of codes Z68.41 and Z68.42.
We request the CMS consider deferring the change in CC status for Z68.41 (BMI 40.0-44.9) and Zz68.42 (BMI45.0-49.9)."

1 https://www.osha.gov/dsg/hospitals/documents/1.2_Factbook_508.pdf
2 https://journalofethics.ama-assn.org/article/safe-patient-handling-laws-and-programs-health-care-workers/2016-04
3 https://www.cdc.gov/obesity/data/adult.html

Downgrading of specific transient ischemic attacks from "CC" to "non-CC"

We disagree with this decision to downgrade vertebral basilar artery syndrome, carotid artery syndrome, multiple and bilateral pre-cerebral artery syndromes and amaurosis fugax to a "non-CC." A hospital should not be penalized for providing the specificity of the transient ischemic attack. In the spirit of ICD – 10, we request that providers be more specific in their designation of the condition or location. These conditions are transient ischemic attacks and contain all of the comorbidities and complications of a transient ischemic attack. For that reason, it should remain a CC.

Downgrading of compression of brain and brain death from an "MCC" to a "CC".

We disagree with this decision. These two conditions should remain as MCCs. In the case of brain compression, patients suffering from this condition are seriously ill. Causes of brain compression can be from tumors, hemorrhage, stroke, postsurgical complications, hydrocephalus, impaired CNS venous outflow and trauma. Compression of the brain, even when treated successfully, can have devastating neurological consequences for the patient. Intense resource utilization occurs with the treatment of this condition. These patients require monitoring of intracranial pressures, blood pressure, and fluid status. They require proper resuscitation, and in emergency situations, may require surgery. They require close monitoring for seizure activity. They may require seizure prophylaxis treatment (1).

A patient who suffers from brain death usually requires intense use of resources and monitoring prior to determination of brain death. To determine if a patient is brain dead, there is often a combination of clinical and diagnostic criteria. Tests may include CT, angiography, MRI, EEG, and /or evoked potentials. These tests are usually beyond the treatment that was provided to the patient prior to the diagnosis of brain death. These patients are severely ill and on the ventilator. Keeping this condition an MCC will appropriately reflect the resources provided to the patient.

1. Smith E and Amin-Hanjani. Evaluation and management of elevated intracranial pressure in adults. Up to date May 2019.)

Downgrading of ST elevation myocardial infarctions from an "MCC" to a "CC"

We disagree with the downgrading of this condition. The literature reports that 60 to 65% of ST elevation myocardial infarctions occur in patients ≥ 65 years old. It is estimated that 28 to 33% occur in patients ≥ 75 years old (1, 2, 3). It is also estimated that 80% of all deaths related to myocardial infarction occur in people who are 65 years old or greater (4). Older patients present atypically and due to that, have a delay in diagnosis (5). The literature demonstrates that the Medicare population is at higher risk for comorbidity, complications and death. For this reason, this should remain an MCC

1. Alexander KP, Newby LK et. al. acute coronary care in the elderly, part II: ST – segment – elevation myocardial infarction: a scientific statement for healthcare professionals from the American Heart Association Council on clinical cardiology: in collaboration with the society of geriatric cardiology. Circulation. 2007; 115(19): 2570.)
2. Goldberg RJ, McCormick D, et. al. Age-related trends in short – and long – term survival after acute myocardial infarction: the 20 – year population – based perspective (1975 – 1995). Am J Cardiol. 1998;82(11):1311
3. Roger VL, Jacobsen SJ et. al. trends in the incidence and survival of patients with hospitalized myocardial infarction, Olmsted County, Minnesota, 1979 to 1994. Ann Intern Med. 2002; 136(5): 341.
4. Reeder GS and Kennedy HL. Up to date May 2019
5. Alexander KP, Newby LK et. al. acute coronary care in the elderly, part II: ST – segment – elevation myocardial infarction: a scientific statement for healthcare professionals from the American Heart Association Council on clinical cardiology: in collaboration with the society of geriatric cardiology. Circulation. 2007; 115(19): 2570.

Downgrading of Chronic systolic, diastolic, and combined chronic systolic and diastolic congestive heart failure from a "CC" to a "non-CC"

We disagree with this decision. First, on a practical level, the unspecified code remains a CC. Again, in the spirit of ICD – 10, we would like to move toward specificity, and this decision deters designation of specificity. On a medical and physiologic level, we disagree with this decision. Patients with both chronic and systolic heart failure has a worse prognosis for survival than those without heart failure (1). Another study demonstrated patients with chronic preserved ejection fraction had a one-year mortality of 22% and those with reduced ejection fraction had a mortality of 26% (2).

Patients with chronic diastolic heart failure often have multiple comorbid conditions including hypertension, lung disease, coronary artery disease, atrial fibrillation, obesity, anemia, diabetes, kidney disease and sleep disordered breathing (3). Patients with chronic systolic heart failure often have associated conditions including tachycardia, arrhythmias, ischemia, valve disorders and renal disease (4). These patients are sicker, have more comorbidities, and require more care. For that reason, this should remain a CC.

1. Metadata – analysis global group in chronic heart failure. The survival of patients with heart failure with preserved or reduced left ventricular ejection fraction: an individual patient data metadata – analysis. Eur Heart J. 2012 Jul; 33(14): 1750 – 7. EPub 2011 Aug 6.
2. Bhatia RS, TU JV et.al. outcome of heart failure with preserved ejection fraction in a population – based study. N Engl J Med. 2006;355(3):260.
3. Mentz RJ et. al. noncardiac comorbidities and heart failure with reduced versus preserved ejection fraction. J Am Coll Cardiol. 2014 Dec;64(21):2281-93. EPub 2014 Nov 24.
4. Colluci W. Overview of the therapy of heart failure with reduced ejection fraction. Up to date. May 2019.

Downgrading of many cardiomyopathies to "non-CC" (Examples: obstructive hypertrophic, Endo myocardial disease, endocardial fibroelastosis, restrictive cardiomyopathy, cardiomyopathy due to sarcoidosis)

We disagree with the decision to downgrade cardiomyopathies to a "non-CC." Cardiomyopathies are diseases that affect the cardiac tissue and muscle. In essence, the muscle is diseased and no longer functions properly. This can lead to many deleterious effects for the patient. It is not uncommon for these patients to develop heart failure, arrhythmias, and outflow obstruction (1, 2). Given the common comorbidities associated with cardiomyopathies, it is essential to have this remain a CC in order to preserve the resources provided to the patients who suffer from this condition.

1. Cooper L. definition and classification of the cardiomyopathies. Up-to-date. May 2019.
2. Maron M. Hypertrophic cardiomyopathy: clinical manifestations, diagnosis, and evaluation. Up-to-date. May 2019.

Downgrading of nontraumatic chronic subdural hemorrhage from an "MCC" to a "CC"

We disagree with this decision to downgrade as this condition is seen more commonly in the elderly population. Older patients have cerebral atrophy as a consequence of the aging process. Those with cerebral atrophy are at higher risk for a subdural hematoma. These patients are much more susceptible to developing a nontraumatic subdural hemorrhage (1, 2). Currently, there are no expert consensus on the treatment of chronic subdural hemorrhage, however, it is highly recommended that these patients undergo surgical evacuation of the hematoma (3). A brain hemorrhage requires expert care, intensive monitoring regardless if it is chronic, acute, traumatic or atraumatic. This condition should remain an MCC.

1. Mayer S, Rowland L. Head Injury. In: Merritt's Neurology, Rowland L (Ed), Lippincott Williams and Wilkins, Philadelphia 2000. P.401
2. Doherty DL. Posttraumatic cerebral atrophy as a risk factor for delayed acute subdural hemorrhage. Arch Phys Med Rehabil. 1988;69(7):542.
3. McBride W. subdural hematoma and adults: prognosis and management. Up-to-date. May 2019.

Downgrading of acute pulmonary insufficiency following thoracic surgery and acute post procedural respiratory failure from an "MCC" to a "CC"

We disagree with the decision to downgrade these two conditions. Patients with these conditions require intensive therapy including, but not limited to, noninvasive positive pressure ventilation or mechanical ventilation. These patients have a prolonged stay in the intensive care unit and the hospital. Increased resources are used to care for these patients and should be reflected by having these codes remain as MCC.

Downgrading of diverticulosis of large intestine without perforation or abscess with bleeding from an "MCC"" to a "CC"

We disagree with this decision to downgrade this condition. The clinical presentation of a patient with bleeding requires intense investigation including ruling out an upper G.I. bleed, blood work, endoscopy and colonoscopy. In addition, aggressive resuscitation with fluids and blood products must be undertaken to prevent shock. In cases where bleeding cannot be identified by colonoscopy, patients require angiography. Some of these patients require surgical intervention. The population most affected by this condition are older patients. The literature reports that these patients typically have other comorbid conditions and for that reason, mortality rates for this condition can be as high as 20% (1, 2, 3, 4). The mortality rate of 20% reflects how ill these patients are, and for that reason, this should remain an MCC.

1. Gostout CJ et. el. Acute gastrointestinal bleeding. Experience of a specialized management team. J Clin Gastroenterol. 1992;14(3):260.
2. Browder W et.al. impact of emergency angiography in massive lower gastrointestinal bleeding. Ann Surg. 1986;204(5):530
3. Uden P et al. influence of selective mesenteric arteriography on the outcome of emergency surgery for massive, lower gastrointestinal hemorrhage. A 15-year experience. Dis Colon Rectum. 1986;29(9):561.
4. Hemberton J. Colonic diverticular bleeding. Up-to-date. May 2019.

Downgrading of Angiodysplasia of the stomach and duodenum with bleeding from an "MCC" to a "CC"

We disagree with the downgrading of this condition from an MCC to a CC. First, this condition is most often seen in patients older than 60 years old. It is usually associated with other conditions such as "end-stage renal disease, von Willebrand disease and possibly aortic stenosis" (1). Like diverticular bleeding, these patients require supportive care including fluids and may require transfusions. Often, they require invasive treatments to diagnose the exact cause of the bleeding. These patients require a higher level of care due to the bleeding, and with their associated comorbidities. This should remain an MCC.

1. Saltzman J. Angiodysplasia of the gastrointestinal tract. Up-to-date. May 2019.

Downgrading of solid organ transplant, bone marrow and stem cell transplant from "CC" to "non-CC"

We disagree with the decision to downgrade these conditions to a "non-CC." Patients who are status post-transplant require more monitoring, medication management and are at a higher risk for other complications and diseases due to their transplant status. Patients who have undergone solid organ transplants or allogenic hematopoietic cell transplantation are at a higher risk of post – transplant lymphoproliferative disorders (PTLD) (1). This condition is associated with immunosuppression, which is absolutely necessary in the treatment of a post-transplant patient. The incidence of developing a lymphoproliferative disorder after transplant is *30 to 50 times higher* than the general population (2,3,4,5).

Transplant patients are at increased risk of infection. Studies have demonstrated that the leading cause of mortality after a liver and renal transplantation is infection (6, 7, 8, 9). Even common infections such as a urinary tract infection or pharyngitis can lead to sepsis with multiorgan failure (10). Liver transplant patients are at risk of metabolic syndrome, acute and chronic renal disease, bone disease, de novo malignancy. Because of these conditions, these patients require higher surveillance. These patients are also at higher risk of central nervous system complications due to immunosuppressive drugs (11). Renal transplant patients are at higher risk of cardiovascular disease. In diabetic renal transplant patients, cardiovascular disease is the major cause of death in graft loss. They are higher risk for bone metabolism and disease, leukopenia, anemia, thrombocytopenia, malignancy, and electrolyte abnormalities.

In general, any transplant recipient is susceptible to infections and cancer. Transplant status, regardless of which organ, marrow or stem cell, is associated with more comorbidities than the normal population. For this reason, transplant status should remain a CC (12).

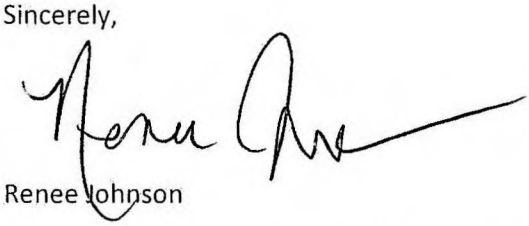
1. Friedberg J and Aster J. epidemiology, clinical manifestations, and diagnosis of post – transplant conferral proliferative disorders. Up-to-date. May 2019.
2. Andreone P. et.al. post transplantation lymphoproliferative disorders. Arch Intern Med. 2003;163(17):199.
3. Caillard S. et.al. post – transplant lymphoproliferative disorders occurring after renal transplantation adults: report of 230 cases from the French registry. Am J Transplant. 2006;6(11):2735.
4. Curtis RE. et. al. risk of lymphoproliferative disorders after bone marrow transplantation: a multimedia – institutional study. Blood. 1999;94(7):2208.
5. 5 Matas AJ et.al. OPTN/SRTR 2013 Annual Data Report:kidney. Am J Transplant. 2015;15 Suppl 2:1.
6. Torbenson M et.al. causes of death in autopsy liver transplant patients. Mod Pathol. 1998;11(1):37.
7. Chang FY, et.al. fever liver transplant recipients: changing spectrum of etiologic agents. Clin infect Dis. 1998;26(1):59
8. Briggs JD. Causes of death after renal transplantation. Nephrol Dial transplant. 2001;16(8):1545.
9. The AST infectious disease community of practice, American Society of transplantation, infectious disease guidelines for transplantation. Am J Transpl. 2009;9 (Suppl 4):S1.
10. McCashland TM. Post transplantation care: role of the primary care physician versus transplant center. Liver Transpl. 2001 Nov;7(11Suppl1):S2-12.
11. Gaglio P and Cotler S. liver transplantation adults: long-term management of transplant recipients. Up to date. May 2019.

12. Chandraker A and Yeung MY. Overview of care of the adult kidney transplant recipient. Up-to-date. May 2019

Conclusion

UPMC appreciates the opportunity to submit these comments on the CMS Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals. If you have any questions concerning our comments, please contact me directly at johnsonr17@upmc.edu or 412-623-6303.cc

Sincerely,



Renee Johnson

Vice President, Corporate Reimbursement